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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,825	01/23/2004	Jan Weber	03-100	5021

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EXAMINER

KOTINI, PAVITRA

ART UNIT PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/763,825	<b>Applicant(s)</b> WEBER ET AL.	
	<b>Examiner</b> Pavitra Kotini	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-63,65,66 and 69-84 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-13, 15, 16, 24, 25, 28, 29-32, 34, 35-38, 50, 52, 54, 56, 57, 60, 61,63, 64, 71-74, 80-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,8,14,17-23,26,27,33,39-49,51,53,55,58,59,62,65,66,69,70 and 75-79.

### DETAILED ACTION

This Office Action is in response to amendment received on December 21, 2006. Cancellation of claim 64, addition of new claims 81-84, and amendments to claims 15, 28, 50 are acknowledged.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-6, 9, 12,13, 16, 24, 25, 29, 34, 36-38, 54, 56, 57, 61, 71, 72, and 80** are rejected under 35 U.S.C. 102(e) as being anticipated by Maseda (US 6514237) for the reasons previously made of record.

Amended **claims 15, 28, and 50** are still rejected under 35 U.S.C. 102(e) as being anticipated by Maseda (US 6514237).

Regarding **claim 15**, Maseda discloses that said catheter is a balloon catheter *that further comprises a balloon* (110, fig. 1; balloon 118, fig. 1).

Regarding **claim 28**, Maseda discloses an elongate body(114, fig. 1), said elongate body having distal (122, fig. 1) and proximal (120, fig. 1) ends and an axis (130, fig. 1); a balloon (118, fig. 1); an active region (composite strands; col.4, lines 44-

Art Unit: 3731

48) comprising an electroactive polymer (col.5, lines 1-19) *disposed over the elongate body and beneath the balloon* (distal end 128 of elongate body 114 which also contains active regions is under balloon 118; col.6, lines 64- col.7, line 1), said active region being adapted to radially advance (col.3, lines 2-6) at least a portion of the balloon when the balloon is in a substantially un-inflated state (col.6, lines 45-51).

Regarding **claim 50**, Maseda discloses a *balloon catheter* (110) comprising: an insertable body (114, fig. 1) adapted for insertion into a body lumen of a patient; a device lumen (inside shaft 114, fig. 2) within said insertable body; *an inflatable balloon, wherein the interior of said balloon is in fluid communication with said device lumen* (130; col.4, lines 21-28); and one or more electrically actuated members disposed along at least a portion of the length of said device lumen (col.6, lines 19-26), said one or more electrically actuated members being inherently capable of transforming at least a portion of the length of said device lumen between (i) a *radially* expanded state and (ii) a *radially* contracted state ( the various configurations and coordinated movements disclosed by Maseda inherently encompass contraction and expansion, in the longitudinal and radial planes; col.3, lines 2-6) in which said insertable body *is* more readily inserted into said body lumen of said patient (col.2, lines 41-62; the electroactive polymer can be manipulated to make it easier to insert the medical device into the body lumen).

New **claim 84** is rejected under 35 U.S.C. 102(e) as being anticipated by Maseda (US 6514237).

Regarding **claim 84**, Maseda discloses the active region is disposed over the elongate body (col.5, lines 20-24) and beneath the balloon (col.6, lines 65-66)

**Claims 81-83** are further rejected under 35 U.S.C. 102(e) as being anticipated by Couvillion Jr. (US 6679836).

Regarding **claim 81**, Couvillon discloses an elongate body (actuator 10 disposed on guide catheter; col.5, lines 53-55; col.6, line 59), said elongate body having distal (a left end) and proximal (a right end) ends and an axis (dotted line, fig. 1); an active region (12) comprising a conductive polymer disposed over the elongate body such that the medical device is expanded in at least one radial dimension relative to said axis upon volumetric expansion of the active region (col.3, lines 2-6; col.4, lines 45-46); an electrolyte (14) in contact with said conductive polymer.

Regarding **claim 82**, Couvillon discloses a counter electrode (18).

Regarding **claim 83**, Couvillon discloses said active region, said electrolyte, and said counter electrode are enclosed within a sealed structure (col.6, lines 58-59).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 10, 11, 30-32, 35, 52, 60, 63, 73, 74** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 65144237) for reasons previously made of record and for the reasons cited above in the independent claims.

### ***Response to Arguments***

Applicant's arguments filed on December 21, 2006 have been fully considered but they are not persuasive. Specifically, claim 1 is broad enough to encompass all the different categories of electroactive polymers, so the rejection by Maseda is still viable. However, claims 81-83 further specify the category of electroactive polymer, so a new reference was required to reject dependent claims 81-83. Claim 84 was still rejectable under the priori art reference previously made of record.

Regarding arguments to claim 1, the Examiner understands the difference in the electroactive polymer types/categories and that different types of EAPs operate in a different manner, however, claim 1 is broad enough to include ionic-exchange polymer-noble metal composites, which are inherently electrically conductive and therefore can also be considered conductive polymers in the broad sense. Furthermore, although it is true that these ion-exchange polymer-noble metal composites undergo deformation in the form of bending, they are also capable of expansion, as disclosed by Maseda (col.3, line 54). The examiner would like to point out that the definition of expansion according to the Academic Press Dictionary of Science and Technology, defines expansion as an increase in volume. Therefore, by Maseda disclosing that the EAP polymer can undergo expansion, it is understood by one of ordinary skill in the art that this expansion includes a volumetric expansion. Lastly, the Examiner would like to refer paragraph [0055] of the

Art Unit: 3731

Applicant's disclosure, where the Applicant discloses, "any electroactive polymer that exhibits contractile or expansible properties may be used in connection with the various active regions of the invention". Hence, the reference of Maseda clearly anticipated each and every element of claim 1.

Regarding claim 28, Maseda does teach that a portion of the balloon can be expanded radially because the distal end of the elongate body, which contains electroactive polymer strands all over the entire length, is positioned beneath the balloon, so when the strands beneath the balloon are activated, the balloon can be inflated by a miniscule force.

Regarding claim 50, Maseda clearly discloses that along the elongate body 114 there is an the inflation lumen 130 that is directly in fluid communication with the interior of the ballon (col.4, lines 21-18).

In general, Maseda discloses that composite strands of electroactive polymer can deform in various configurations including expansion (col.3, line 54) and expansion like a balloon (col.3, lines 4-5). Hence, it is inherent that the strands that are embedded over the elongate body and beneath the balloon will also perform in this manner.

Lastly, the Examiner would like to point out that claim 1 is so broad that it can interpreted such that the active region can be the balloon itself. In other words, the reference of Maseda anticipates the limitations of claim 1 such that a elongate body (114) has an active region (balloon 118) comprising a conductive polymer (composite strands 306, 308, 400, 500) disposed over the elongate body (114) such that the medical device (balloon catheter) is expanded (due to expansion of the balloon) in at



least one radial dimension relative to said axis upon volumetric expansion of the active region (balloon 118).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

P.Kotini  
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3/16/07

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

*3/16/07*